IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	:	3:09-md-02100-DRH-PMF MDL No. 2100
KAYLA ALLISON DAVIS	:	Judge David R. Herndon
Plaintiff,	:	COMPLAINT AND JURY DEMAND Civil Action No.: 3:11-cv-13404-DRH-PMF
vs.	:	
BAYER CORPORATION, an Indiana Corporation c/o Illinois Corporation Service C 801 Adlai Stevenson Dr. Springfield, IL 62703,	:	
BAYER HEALTHCARE PHARMACEUTICALS INC., a Delaware corporation c/o Illinois Corporation Service C 801 Adlai Stevenson Dr. Springfield, IL 62703,	:	
BAYER HEALTHCARE, LLC, a Delaware corporation c/o Illinois Corporation Service C 801 Adlai Stevenson Dr. Springfield, IL 62703,	:	

BAYER PHARMA AG, :
Müllerstrasse 178
13353 Berlin, Germany :

BAYER AG, :
Leverkusen
North Rhine-Westphalia, Germany :

Defendants. :

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COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, KAYLA ALLISON DAVIS, through her undersigned attorneys Levin, Papantonio et al., sues Defendants, and alleges as follows:

PARTIES AND JURISDICTION

1. Plaintiff Kayla Allison Davis ("Plaintiff") at all times relevant was a resident and citizen of Tallassee, Alabama, located in Elmore County, Alabama.

2. Plaintiff was prescribed and ingested Yaz and while using Yaz suffered a serious and permanent injury.

3. Plaintiff alleges an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

4. Defendant Bayer Corporation is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant Bayer Corporation is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into

interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz and Yasmin. At all relevant times, Defendant Bayer Corporation conducted regular and sustained business in Illinois by selling and distributing its products throughout the state of Illinois and throughout the United States.

5. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Bayer Healthcare Pharmaceuticals, Inc. was created by the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare Pharmaceuticals, Inc. is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz and Yasmin. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. conducted regular and sustained business in Illinois by selling and distributing its products throughout the state of Illinois and throughout the United States.

6. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for YAZ®.

7. Defendant Bayer Healthcare Pharmaceuticals, Inc., is the holder of the approved New Drug Application ("NDA") for YASMIN®.

8. Defendant Bayer Healthcare, LLC is a Delaware limited liability company, with its principal place of business at 555 White Plains Road, Tarrytown, New

York 10591. Bayer Healthcare, LLC was involved in the integration of Bayer Healthcare and Berlex Laboratories. Defendant Bayer Healthcare, LLC is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz and Yasmin. At all relevant times, Defendant Bayer Healthcare, LLC conducted regular and sustained business in Illinois by selling and distributing its products throughout the state of Illinois and throughout the United States.

9. Berlex Laboratories International, Inc. was a Delaware corporation with its principal place of business in Montville, New Jersey. Berlex Laboratories International, Inc. was integrated with Bayer Healthcare, leading to the creation of Bayer Healthcare Pharmaceuticals, Inc. Prior to being integrated with Bayer Healthcare to create Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories International, Inc. was engaged in the business of researching, developing, designing, licensing, manufacturing, supplying, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drugs Yaz and Yasmin. At all relevant times, Berlex Laboratories International, Inc. conducted regular and sustained business in Illinois by selling and distributing its products throughout the state of Illinois and throughout the United States.

10. Defendant Bayer Pharma AG formerly known as Bayer Schering Pharma AG also formerly known as Schering AG, is a pharmaceutical company that is organized

and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

11. Defendant Bayer Pharma AG, is a corporate successor of Bayer Schering Pharma AG and Schering AG.

12. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006.

13. Bayer Schering Pharma AG was renamed Bayer Pharma AG effective July 5, 2011.

14. Defendant Bayer Pharma AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh Pennsylvania 15205.

15. Defendant Bayer Schering Pharma AG is the current owner of the patent(s) relating to the oral contraceptive, YASMIN®.

16. Defendant Bayer Schering Pharma AG, is the current owner of the patent(s) relating to the oral contraceptive YAZ®.

17. Defendant Bayer AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

18. Defendant Bayer AG is the third largest pharmaceutical company in the world.

19. Defendant Bayer AG is the parent/holding company of all other named Defendants.

20. Defendant Bayer AG's headquarters and principal places of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

21. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

22. This Court has personal jurisdiction over Defendants consistent with the United States Constitution by virtue of Defendants' substantial, continuous and systematic contacts with the State of Illinois.

23. Venue in this district is appropriate under 28 U.S.C. §1391(a) and (c) because Defendants are subject to personal jurisdiction in this venue. Furthermore, Plaintiff files this Complaint in this district pursuant to Case Management Order No. 9 entered by the honorable Judge David R. Herndon in MDL No. 2100.

FACTUAL BACKGROUND

Nature of the Case

24. Plaintiff Kayla Allison Davis ("Plaintiff") brings this case against Defendants for damages associated with her ingestion of the pharmaceutical drug Yaz, which is an oral contraceptive designed, manufactured, supplied, marketed, and distributed by Defendants. Specifically, as a direct result of her use of Yaz, Plaintiff suffered a serious and permanent injury.

Bayer's Combined Oral Contraceptives – Yaz, Yasmin and Ocella

25. Yaz and Yasmin are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain

an estrogen component and a progestin component. These hormonal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

26. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

27. The estrogen component in Yaz and Yasmin is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

28. Yaz and Yasmin are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that had never before been marketed in the United States and is unlike any other progestin available in the United States.

29. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

30. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. levonorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol,

helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

31. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a warning of the potentially increased risk of thrombosis.

32. Yaz and Yasmin contain the same estrogen component, ethinyl estradiol, which has been used in the lower dose birth control pills for decades.

33. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for Yaz, Yasmin and Ocella, the generic version of Yasmin.

34. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and are potentially more dangerous.

35. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance the clotting effects of estrogen as do other progestins, particularly the second generation progestins.

36. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

37. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

38. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

39. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products, including reports of gallstones and gallbladder disease.

40. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

41. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism including two deaths where Yasmin was suspected as the cause.

42. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.

43. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

44. Some deaths reported occurred in women as young as 17 years old.

45. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

46. Two recent studies, released in August 2009, have found significantly increased risks of harm associated with Yasmin or Yaz compared to other types of birth control pills. The first study assessed the risk of developing venous thrombosis in women who use oral contraception. The women ranged in age from 15 to 49 and had no history of heart disease or any malignant condition. The study found that of the 3.3 million women taking oral contraceptives, there were 4,213 venous thrombotic events. Of this total, 2,045 occurred in women using drospirenone oral contraceptives. The study concluded "oral contraceptives with…drospirenone were associated with a significantly higher risk of venous thrombosis than other oral contraceptives with levonorgestrel". Lidegard, *et al.*, *Hormonal contraception and risk of venous thromboembolism: national follow up study*, THE BRITISH MEDICAL JOURNAL 2009, 330:B2921.

47. The study found that Yasmin and Yaz users have twice the risk of a clotting event than users of birth control pills that contain levonorgestrel.

Vandenbroucke, *et al.*, *The venous thrombotic risk of oral contraceptives, effects of estrogen dose and progestin type: results of the MEGA case-control study.* THE BRITISH MEDICAL JOURNAL 2009, 339:B2921.

Over-Promotion of Yasmin and Yaz

48. Defendants market Yaz and Yasmin as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

49. However, because Yaz and Yasmin contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

50. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

51. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence or substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

52. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

53. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the more serious condition of premenstrual dysphoric disorder or "PMDD."

54. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

55. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone … which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

56. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

57. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

58. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

Plaintiff's Use of Yaz and Resulting Injuries

59. Plaintiff's medical provider prescribed and Plaintiff ingested Yaz.

60. While taking Yaz Plaintiff suffered a serious and permanent injury.

61. As a direct and proximate result of using Yaz Plaintiff suffered the injury described above.

62. Prior to and at the time of Plaintiff's use of Yaz, Defendants knew or should have known that use of Yaz or Yasmin created a higher risk of serious side effects such as DVT, PE, arrhythmia, hyperkalemia, gallbladder disease, and organ failure than with other oral contraceptives on the market, and when taken as directed these products were unreasonably dangerous to consumers.

63. Despite the fact that Defendants knew or should have known of the serious increased health risks associated with the use of Yaz, Defendants failed to adequately warn Plaintiff and/or her health care providers of these increased risks before she used the product.

64. Had Plaintiff and/or her heath care providers known of the increased risks and dangers associated with Yaz, she would not have used this product and would not have suffered a serious and permanent injury.

65. As a direct and proximate result of her use of Yaz, Plaintiff has suffered significant harm, conscious pain and suffering, permanent physical injury and bodily impairment, including but not limited to a serious and permanent injury, which will have side effects and consequences that will continue to affect her throughout her lifetime.

66. Further, as a direct and proximate result of her use of Yaz Plaintiff has suffered significant mental anguish and emotional distress and will continue to suffer

physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

67. Plaintiff has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yaz.

FIRST CAUSE OF ACTION

Strict Products Liability
Defective Manufacturing

68. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

69. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of Yaz.

70. The Yaz oral contraceptives manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were defective in their manufacture and construction such that they were unreasonably dangerous, were not fit for the ordinary purpose for which they were intended, and/or did not meet the reasonable expectations of an ordinary consumer.

71. The Yaz oral contraceptives manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction as described at the time they left the Defendants' control.

72. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants,

Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

73. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability
Defect in Design or Formulation

74. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

75. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.

76. The Yaz oral contraceptives manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were defective in their design such that they were unreasonably dangerous, were not fit for the ordinary purpose for which they were intended, and/or did not meet the reasonable expectations or an ordinary consumer.

77. At the time Defendants manufactured, designed, distributed, sold, and/or supplied the Yaz oral contraceptives into the stream of commerce, a safer, more practical, alternative design was available.

78. The Yaz oral contraceptives manufactured, designed, sold, distributed, supplied, and/or placed in the stream of commerce by Defendants, were defective in design as described above at the time it left the Defendants' control.

79. As a direct and proximate result of Plaintiff's use Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

80. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability
Defect Due to Inadequate Warning

81. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

82. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz.

83. The Yaz oral contraceptives manufactured and supplied by Defendants were defective due to inadequate warning or instruction, because Defendants knew or should have known that the products were unreasonably dangerous in that they created a substantial increased risk of serious bodily harm and death to reasonably foreseeable

consumers such as Plaintiff, and Defendants failed to adequately warn consumers and/or their health care providers of such increased risk.

84. The Yaz oral contraceptives manufactured and supplied by Defendants were also defective due to inadequate post-marketing warning or instruction, because, after Defendants knew or should have known of the increased risk of serious bodily harm and death from the use of Yaz, Defendants failed to provide adequate warning to consumers and/or their health care providers of these products, knowing these products could cause serious injury and death.

85. As a direct and proximate result of Plaintiff's use of Yaz as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

86. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Strict Products Liability
Defect Due to Nonconformance with Representations

87. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

88. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Yaz, and they made representations regarding the character or quality of this product.

89. The Yaz manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning these products.

90. Plaintiff and/or her prescribing physician justifiably relied upon Defendants' representations regarding Yaz when plaintiff's physician prescribed and Plaintiff used Yaz.

91. As a direct and proximate result of Plaintiff's use of Yaz and or Plaintiff's physician's reliance on Defendants' representations regarding the character and quality of these products, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

92. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Strict Products Liability
Defect Due to Failure to Adequately Test

93. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

94. Defendants advised consumers and the medical community that Yaz contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yaz versus other oral hormonal birth control pills.

95. Had Defendants adequately tested the safety of Yaz versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiff would not have used, and her physician would not have prescribed Yaz.

96. As a direct and proximate result of Defendants' failure to adequately test the safety of Yaz versus other oral hormonal birth control pills, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

97. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Negligence

98. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

99. Defendants had a duty to exercise reasonable care in the manufacture, design, sale, distribution, supply, marketing, and/or placement of Yaz into the stream of commerce, including a duty to ensure that its products did not pose a significantly increased risk of bodily harm and adverse events.

100. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Yaz into interstate commerce in that Defendants knew, or

should have known, that these products caused such significant bodily harm or death and were not safe for use by consumers.

101. Defendants also failed to exercise ordinary care in the labeling of Yaz and failed to issue to consumers and/or their health care providers adequate warnings of the increased risk of serious bodily injury or death due to the use of these products.

102. Despite the fact that Defendants knew or should have known that Yaz posed a serious increased risk of bodily harm to consumers, Defendants continued to manufacture and market these products for use by consumers.

103. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

104. As a direct and proximate result of Defendants' negligence, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

105. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

SEVENTH CAUSE OF ACTION

Breach of Express Warranty

106. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

107. Defendants expressly warranted that Yaz were safe and effective prescription oral contraceptives.

108. The Yaz birth control products manufactured and sold by Defendants did not conform to these express representations because they caused serious injury to consumers who used these products when taken in the recommended dosages.

109. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

110. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

EIGHTH CAUSE OF ACTION

Breach of Implied Warranty

111. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

112. At the time Defendants manufactured, marketed, sold, and distributed Yaz, Defendants knew of the use for which these products were intended and impliedly warranted Yaz to be of merchantable quality, fitness, and safe for such use.

113. Plaintiff and her health care provider reasonably relied upon the skill and judgment of Defendants as to whether Yaz was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

114. Contrary to the implied warranty, Defendants' products Yaz were not of merchantable quality or safe for their intended use, because they were unreasonably dangerous as described herein.

115. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

116. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

NINTH CAUSE OF ACTION

Negligent Misrepresentation and/or Fraud

117. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

118. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Yaz and, while engaged in the course of such business, made representations to Plaintiff and her physician regarding the character and/or quality of these products for guidance in their decision to select Yaz for Plaintiff's use.

119. Specifically, Defendants represented that Yaz was just as safe, and just as effective or more effective, than other birth control products on the market.

120. Defendants' representations regarding the character or quality of Yaz were untrue.

121. Defendants had actual knowledge based upon studies, published reports and clinical experience that Yaz created an unreasonable increased risk of serious bodily injury and death to consumers, or should have known such information.

122. Defendants negligently and/or intentionally misrepresented or omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe and effective in order to avoid losses and sustain profits in its sales to consumers.

123. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to the intended recipients, including Plaintiff and her physician.

124. Plaintiff and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in their labeling, advertisements, and promotions concerning the serious risks posed by Yaz. Plaintiff and her health care provider reasonably relied upon Defendants' representations that Yaz was just as safe and effective as other types of oral contraceptives and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

125. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

126. Defendants' conduct as alleged in this Complaint demonstrates that Defendants were grossly negligent. Furthermore, Defendants acted willfully, wantonly and or maliciously so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Exemplary damages;

4. Attorneys' fees, expenses, and costs of this action; and

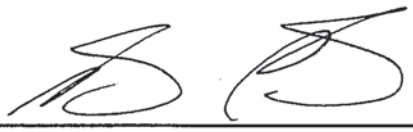
5. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: November 29, 2011

Respectfully submitted,



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